



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 750,031	12 29 2000	Lucas J.C. Van Loon	276550 BO-43213 ACW	6442

22242 7590 02 08 2002

FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
----------	--------------

1651

DATE MAILED: 02 08 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/750,031

Applicant(s)

SIEMENSMA ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1651

DETAILED ACTION

Applicant's amendment filed November 29, 2001 has been received and entered into the case. Claims 1 – 16 have been cancelled and claims 17 – 40 have been entered. Claims 17 – 40 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 17 – 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 and its dependents are drawn to a composition, however are rendered vague and indefinite because it is unclear if each ingredient (i.e. carbohydrate, peptide material and amino acid) is in an amount between 0.2 – 20%, or if only the selected amino acid (i.e. leucine and/or phenylalanine) is in an amount between 0.2 – 20%.

The claims are further indefinite for reciting “wherein each are present” because it is unclear if only one amino acid is included or if both must be included in the composition.

In claim 18, “the additional free amino acid” lacks sufficient antecedent basis.

Art Unit: 1651

Claim 18 is rendered vague and indefinite because it is unclear if both leucine and phenylalanine are required in the composition or if only one of leucine or phenylalanine is required.

Claim 20 is rendered vague and indefinite because it is unclear if both arginine and glutamine are required in the composition or if only one of arginine or glutamine is required.

Claim 33 is rendered vague and indefinite for depending on a cancelled claim. It is unclear what the composition comprises, as the scope is not clearly set forth. The claim will be interpreted as dependent on claim 17.

Claim 35 is rendered vague and indefinite for reciting "wherein said composition comprises" because it is unclear if the composition further comprises an isotonic beverage or sports bar, or if the composition rather comprises an isotonic beverage or sports bar.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 17, 19 – 21, 26 – 33, 35 and 39 – 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Portman (US 6051236).

Art Unit: 1651

Applicant claims a composition comprising carbohydrate material, peptide material and at least one free amino acid selected from leucine or phenylalanine wherein the amino acids are present at 0.2 – 20 wt %. The composition further comprises free amino acids selected from arginine or glutamine, present in amounts of 0.1 – 20 wt %. The peptide material derived from wheat, rice, pea, casein, whey proteins or mixtures thereof, and is present in amounts of 0.1 – 50 wt %, or 2 – 25 wt %. The carbohydrate material is selected from monosaccharides, disaccharides or oligosaccharides or a complex edible carbohydrate, specifically maltodextrine and is present in amounts of 10 – 90 wt % or 50 – 80 wt %. The composition further comprises at least one of vitamins, flavors, minerals, lipids, and proteins and is an isotonic beverage or sports bar. Applicant additionally claims a method of feeding, the method comprising enterally administering the composition of claim 17, 36, 37 or 38 to a human and a method of enhancing blood insulin level, the method comprising administering the composition of claim 17, 36, 37 or 38 to a human during or following physical exercise.

Portman teaches a composition comprising carbohydrates, protein (or peptide material) and free amino acids (abstract) selected from leucine (col.5 line 10-15), glutamine, arginine (abstract). Specifically, the carbohydrates include maltodextrins, disaccharides and polysaccharides in amounts from 66 – 88 wt %, proteins include whey or casein proteins in amounts from 17 – 22 wt %, and free amino acids include glutamine, arginine and leucine in amounts from 0.5 – 5 wt % (Table A). The composition additionally includes vitamins, flavors and minerals (Table A) and may be a liquid beverage or sports bar (col.19 line 29-34). Portman teaches that the compositions are used to stimulate insulin levels post exercise (col.19 line 17-21) and facilitate synthesis of glucose into glycogen (abstract).

Art Unit: 1651

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 17, 21 – 25, 33 – 34 and 36 – 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portman (US 6051236).

Applicant claims a composition comprising carbohydrate material, peptide material and at least one free amino acid selected from leucine or phenylalanine wherein the amino acids are present at 0.2 – 20 wt %. The peptide material is derived from wheat, rice, pea, casein, whey proteins or mixtures thereof and has an average peptide chain length of 20 – 40 amino acids, or 3

Art Unit: 1651

– 20 amino acids. The peptide material is obtained by hydrolyzing protein material and is derived from wheat protein. The composition further comprises at least one of vitamins, flavors, minerals, lipids, and proteins, wherein the lipid is an emulsifier. The composition contains 10 – 90 w % carbohydrate, 0.1 – 50 wt % peptide material and 0.2 – 20 wt % of each free amino acid.

Portman teaches a composition comprising carbohydrates, protein (or peptide material) and free amino acids (abstract) selected from leucine (col.5 line 10-15), glutamine, arginine (abstract). Specifically, the carbohydrates include maltodextrins, disaccharides and polysaccharides in amounts from 66 – 88 wt %, proteins include whey or casein proteins in amounts from 17 – 22 wt %, and free amino acids include glutamine, arginine and leucine in amounts from 0.5 – 5 wt % (Table A). The composition additionally includes vitamins, flavors and minerals (Table A) and may be a liquid beverage or sports bar (col.19 line 29-34).

Portman does not teach the composition wherein the peptide chain length is 20 – 40 or 3 – 20 amino acids. However, it would have been obvious to one of ordinary skill in the art to optimize such variables, because it was routine practice in the art at the time the claimed invention was made. Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the particular chain lengths of the peptides of Portman with a reasonable expectation for obtaining a nutritional beverage, bar or composition.

Portman does not specifically teach a hydrolyzed peptide derived from wheat protein or the composition containing a lipid emulsifier. However, at the time the claimed invention was made, it would have been obvious to one of ordinary skill in the art to use a hydrolyzed wheat protein because they were commonly used in the art. In addition, emulsifiers were commonly

Art Unit: 1651

used in such nutritious compositions. In support, Kingham teaches nutritional compositions containing carbohydrates, amino acids and proteins selected from wheat and milk wherein the proteins are hydrolyzed (p.8). The composition of Kingham additionally contains emulsifiers (p.12). In further support, Wilbert teaches nutritional compositions comprising carbohydrates, protein (col.1 line 60 – col.2 line 15) and free amino acids (col.4 line 19-22) wherein the protein (or peptide material) is hydrolyzed from whey or casein protein (col.4 line 22-26). The nutritional compositions of Wilbert further contains emulsifiers (col.5 line 11-12) and lipids (col.3 line 60-65).

8. Claims 17 – 22, 24 – 28, 21 – 34 and 36 – 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilbert et al. (US 5,776,887).

Applicant claims a composition comprising carbohydrate material, peptide material and at least one free amino acid selected from leucine or phenylalanine wherein the amino acids are present at 0.2 – 20 wt % or wherein both leucine and phenylalanine are present each in an amount between 1 – 10wt %. The composition further comprises free amino acids selected from arginine or glutamine in amounts of 0.1 – 20 wt %. The peptide material is derived from wheat, rice, pea, casein, whey proteins or mixtures thereof and is obtained by hydrolyzing the protein material. The peptide has an average peptide chain length of 20 – 40 amino acids or 3 – 20 amino acids and is present in amounts of 0.1 – 50 wt % or 2 – 25 wt %. The carbohydrate material is selected from monosaccharides, disaccharides or oligosaccharides and is present in amounts of 10 – 90 wt % or 50 – 80 wt %. The composition further comprises at least one of vitamins, flavors, minerals, lipids, and proteins wherein the lipid is an emulsifier and the

Art Unit: 1651

composition is an isotonic beverage or sports bar. Specifically, the composition contains 10 – 90 wt % carbohydrate, 0.1 – 50 wt % peptide material and 0.2 – 20 wt % of each free amino acid.

Applicant additionally claims a method of feeding, the method comprising enterally administering the composition of claim 17, 36, 37 or 38 to a human.

Wilbert teaches nutritional compositions comprising a carbohydrate, fat and protein component (col.1 line 60 – col.2 line 15) wherein additional free amino acids selected from leucine, phenylalanine, arginine and glutamine (col.4 line 19-22) are added. The amino acids present in high percentage amounts, greater than 40% (col.4 line 35-40), the protein, or peptide material is hydrolyzed from whey or casein protein (col.4 line 22-26) and the carbohydrate is selected from monosaccharides, disaccharides and polysaccharides (col.2 line 1-11). The nutritional compositions of Wilbert et al. further contain vitamins, minerals (col.4 line 44-46), emulsifiers (col.5 line 11-12), flavors (col.5 line 19-21) and lipids (col.3 line 60-65). Wilbert et al. teach the compositions wherein they are liquid enteral formulations (col.5 line 39-41) utilized for clinical purposes (abstract).

Wilbert does not teach the composition comprising the specific amounts of carbohydrates, protein and amino acids or peptide chain lengths as claimed. However, it would have been obvious to one of ordinary skill in the art to optimize such variables, as it was routine practice in the art at the time the claimed invention was made. Moreover, one of ordinary skill in the art would have been motivated by routine practice to optimize the volumes of Wilbert with a reasonable expectation for obtaining a healthful, nutritious composition.

Applicant argues that Wilbert teaches the composition including fibers, which is essential to the composition and that there is no teaching to omit fiber from the composition.

Art Unit: 1651

However, these arguments fail to persuade because the claimed invention indicates the composition comprises the recited limitations, to include at least those and anything added. Furthermore, Wilbert specifically teaches a healthful composition containing the claimed ingredients.

9. Claims 17 – 22, 24 – 33 and 35 – 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kahn et al. (EP 0 421 309 A2).

Applicant claims a composition comprising carbohydrate material, peptide material and at least one free amino acid selected from leucine or phenylalanine wherein the amino acids are present at 0.2 – 20 wt % or wherein both leucine and phenylalanine are present each in an amount between 1 – 10wt %. The composition further comprises free amino acids selected from arginine or glutamine in amounts of 0.1 – 20 wt %. The peptide material is derived from wheat, rice, pea, casein, whey proteins or mixtures thereof and is obtained by hydrolyzing protein material. The peptide has an average peptide chain length of 20 – 40 amino acids or 3 – 20 amino acids and is present in amounts of 0.1 – 50 wt % or 2 – 25 wt %. The carbohydrate material is selected from monosaccharides, disaccharides or oligosaccharides, specifically a complex edible carbohydrate comprising maltodextrine and is present in amounts of 10 – 90 wt % or 50 – 80 wt %. The composition further comprises at least one of vitamins, flavors, minerals, lipids, and proteins and is an isotonic beverage or sports bar. Specifically, the composition contains 10 – 90 w % carbohydrate, 0.1 – 50 wt % peptide material and 0.2 – 20 wt % of each free amino acid. Applicant additionally claims a method of feeding, the method comprising enterally administering the composition of claim 17, 36, 37 or 38 to a human.

Art Unit: 1651

Kahn teaches compositions containing casein and/or soy protein hydrolysates combined with whey protein hydrolysates and amino acids (abstract). The hydrolysates are obtained by hydrolysis of the protein (p.2 line 15-20). The whey protein hydrolysate comprises 40 – 60 wt % if its amino acids as oligopeptides having 4 – 10 amino acids (p.4 line 5-10). The amino acids are in free form and comprise less than 3.5 % by weight (p.5 line 14-20) and may include arginine, glutamine, leucine and phenylalanine (p.8 line 30-50). The composition further includes carbohydrates (particularly maltodextrines p.6 line 8-9), fatty acids (triglyceride oils and phospholipids, p.6 line 25), vitamins, minerals (p.5 line 54-56) and flavorants (p.6 line 53). The compositions are disclosed for enteral use as well as aqueous liquids, food supplements, complete diet and therapeutic nutrition (p.6 line 12-19).

Kahn does not teach the composition comprising the specific amounts of carbohydrates, protein and amino acids or peptide chain lengths as claimed. However, it would have been obvious to one of ordinary skill in the art to optimize such variables, as it was routine practice in the art at the time the claimed invention was made. Moreover, one of ordinary skill in the art would have been motivated by routine practice to optimize the volumes of Kahn with a reasonable expectation for obtaining a healthful, nutritious composition.

Applicant argues that Kahn does not teach free leucine and/or phenylalanine which are required to stimulate glycogen synthesis and that Kahn teaches the composition for regulating protein metabolism, not carbohydrate metabolism.

However, these arguments fail to persuade because Kahn specifically teach free amino acids (p.5 line 14-20) including leucine and phenylalanine (p.8 line 30-50). In addition, at the time of the invention, free amino acids were known to stimulate glycogen synthesis (see Portman,

Art Unit: 1651

abstract). Although Kahn does not specifically disclose that the composition regulates carbohydrate metabolism, Kahn does teach the composition. It is noted that the claims are drawn to a composition, not a method for regulating carbohydrate metabolism.

10. Claims 17 – 19 and 21 – 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kingham (WO 95/22909).

Applicant claims a composition comprising carbohydrate material, peptide material and at least one free amino acid selected from leucine or phenylalanine wherein the amino acids are present at 0.2 – 20 wt % or wherein both leucine and phenylalanine are present each in an amount between 1 – 10wt %. The composition further comprises free amino acids selected from arginine or glutamine. The peptide material is derived from wheat, rice, pea, casein, whey proteins or mixtures thereof and is obtained by hydrolyzing protein material. Specifically, the peptide material is derived from wheat protein, has an average peptide chain length of 20 – 40 amino acids or 3 – 20 amino acids and is present in amounts of 0.1 – 50 wt % or 2 – 25 wt %. The carbohydrate material is selected from monosaccharides, disaccharides or oligosaccharides or a complex edible carbohydrate, specifically maltodextrine, and is present in amounts of 10 – 90 wt % or 50 – 80 wt %. The composition further comprises at least one of vitamins, flavors, minerals, lipids, and proteins wherein the lipid is an emulsifier and wherein the composition is an isotonic beverage or sports bar. Specifically, the composition contains 10 – 90 w % carbohydrate, 0.1 – 50 wt % peptide material and 0.2 – 20 wt % of each free amino acid. Applicant additionally claims a method of feeding, the method comprising enterally administering the composition of claim 17, 36, 37 or 38 to a human.

Art Unit: 1651

Kingham teaches nutritional compositions containing a carbohydrate, a protein (or peptide material) and amino acids selected from arginine, phenylalanine and leucine (abstract). Carbohydrates include monosaccharides, disaccharides and polysaccharides such as dextrose, maltose, sucrose and maltodextrines (p.6). The protein source is selected from wheat, peas, beans, and milk (casein, whey) and is in the hydrolyzed form (p.8). The composition additionally contains a fat component wherein the fat is phospholipids, triacylglycerols or sterols (p.10), vitamins, minerals, flavoring agents, emulsifiers, and preservatives (p.12). The compositions of Kingham are prepared in liquid and/or bar forms (p.13-14). Example 4 teaches a composition containing maltodextrine, sugar, dextrose, hydrolyzed gelatin, lecithin, vanilla flavoring and a vitamin/mineral mix wherein arginine, phenylalanine and leucine are represented. Example 5 teaches a composition containing dextrose, maltodextrin, sugar, oils, hydrolyzed gelatin, vitamin/mineral mix, lecithin, flavoring and citric acid (antioxidant) wherein arginine, phenylalanine and leucine are represented.

Kingham does not teach the composition comprising the specific amounts of carbohydrates, protein and amino acids or peptide chain lengths as claimed. However, it would have been obvious to one of ordinary skill in the art to optimize such variables, as it was routine practice in the art at the time the claimed invention was made. Moreover, one of ordinary skill in the art would have been motivated by routine practice to optimize the volumes of Kingham with a reasonable expectation for obtaining a healthful, nutritious composition.

Applicant argues that Kingham does not teach the composition containing additional free leucine and/or phenylalanine. Applicant further argues that Kingham teaches the composition

Art Unit: 1651

for protein management that allows amino acids to cross the blood brain barrier, not for inducing an insulin response for stimulating glycogen synthesis.

However, these arguments fail to persuade because Kingham specifically teaches that additional, individual (or free) amino acids can be added to the compositions in order to obtain the disclosed ratios (p.9), thereby suggesting additional free amino acids. Furthermore, although Kingham does not teach the composition for inducing an insulin response, the reference does teach the composition. It is noted that the claims are drawn to a composition, not a method for inducing insulin response for stimulation glycogen synthesis.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
January 29, 2002



LEON S. LANAT
PRIMARY EXAMINER